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| 09/847,102      | 05/01/2001  | Dennis A. Carson     | 066778-0397         | 5759             |

41552 7590 08/19/2009  
MCDERMOTT, WILL & EMERY  
11682 EL CAMINO REAL  
SUITE 400  
SAN DIEGO, CA 92130-2047

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| EXAMINER |
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YU, MISOOK

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1642

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|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

08/19/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SIP\_Docket@mwe.com

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/847,102 | <b>Applicant(s)</b><br>CARSON ET AL. |  |
|                              | <b>Examiner</b><br>MISOOK YU         | <b>Art Unit</b><br>1642              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 16, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 16, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-8, 16, 28, and 29 are pending and under consideration.

#### ***Claim Rejections - 35 USC § 102***

Claims 1-8, 16, 28 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Sen et al., #161 of IDS filed on 08/04/2003, Arthritis & Rheumatism vol. 44, pages 772-781.

Claims 1-8, 16, 28, and 29 are drawn to a purified antibody binds to an epitope at the N-terminal extracellular domain (SEQ ID NO: 68) or pharmaceutical comprising said antibody, wherein the antibody inhibits growth of a malignant cell expressing a frizzled 5 receptor.

Applicant argues the claims require that the recited antibody specifically binds to at least one epitope in an amino terminal extracellular domain of the frizzled 5 receptor expressed on a malignant cell and inhibits growth of the malignant cell that expresse the receptor. Applicant argues that Sen et al., used human frizzled-5 spanning residues 197 to 218 to prepare the polyclonal antibodies but there is no basis to assert that the polyclonal antibodies described by Sen et al., .which were raised using a very small portion of SEQ ID NO:68, inhibit the growth of a malignant cell. Since only a 20 amino acid peptide was injected into rabbits, any epitope recognized by the polyclonal antibodies must fall within this limited region and it is not clear that these antibodies have the characteristic of growth inhibition of a malignant cell.

These arguments have been fully considered but found unpersuasive.

Sen et al., teaches that the Wnt and Fz family proteins have been shown to cause both cell proliferation and cell activation and Wnt/Fz-mediated cell proliferation

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has usually involved nuclear translocation of the multifunctional protein  $\beta$ -catenin. This teaching is same disclosed in the instant the specification (note Fig. 1). One of skill in the art reading Sen et al., would recognize inhibiting Wnt signaling by the antibody binding to human frizzled-5 spanning residues 197 to 218 would able to inhibit cell proliferation.

***Claim Rejections - 35 USC § 103***

Claims 1-8, 16, 28, and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al (IDS, #1711998, Proc. Natl. Acad. Sci. USA. vol. 95, pages 10164-9) in view of US Pat. 5,677,171 (IDS, Hudziak et al., Oct. 14, 1997).

Claims 1-8, 16, 28, and 29 are drawn to a purified antibody binds to an epitope at the N-terminal extracellular domain (SEQ ID NO: 68) or pharmaceutical comprising said antibody, wherein the antibody inhibits growth of a malignant cell expressing a frizzled 5 receptor.

Applicants argue that the Office is impermissibly comparing the Tanaka et al. reference to the Applicants' disclosure. It is Applicants' claims that are rejected and that have to be compared to any cited references. Whether or not the specification includes frizzled 2 data is irrelevant to the question of whether or not Tanaka et al., in combination with Hudziak et al., which effectively describes conditions for producing antibodies that are based on known tumor enhancing growth factor activities of the targets that do not include the frizzled 5 receptor, render obvious the claimed invention.

These arguments have been fully considered but found unpersuasive because the main discovery of Tanaka et al, is amino acids composition discovery of human

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frizzled 5 protein including the extracellular domain. Tanaka et al., at the paragraph bridging pages 10164-5 teach that N-terminal extracellular domain of a frizzled receptor lies just before the first transmembrane helix, also teach “the ectodomain of Fz functions as natural antagonist of Fz-mediated signal transduction”. Tanaka et al., at page 10164 teach Wnt binds to Frizzled family of seven-transmembrane proteins, and the seven-transmembrane proteins frizzled family proteins act as receptors for “Wnt oncoprotein” (see page 10164, left column). Note this teaching with the teachings of the instant specification at page 21-22: it is almost identical. Thus, teaching of Tanaka et al., suggest frizzled member proteins in tumor development and importance of extracellular domain of frizzled receptor for receptor-mediated signal for wnt-mediated oncogenic process. The disclosure of Tanaka et al., is similar in that the instant specification discloses frizzled 2 data (Fig. 5 and 6), while Tanaka et al., discloses frizzled 3 data. Both the instant application and Tanaka et al., connects any Frizzled to Wnt signaling in terms of cancer development or cancer therapeutics.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU  
Primary Examiner  
Art Unit 1642

/MISOOK YU/  
Primary Examiner, Art Unit 1642